Reducing tobacco use, especially cigarette smoking, is a public health priority. The American Stop Smoking Intervention Study (ASSIST) was initiated in 1991 to prevent and reduce tobacco use primarily through policy-based approaches to alter the social-political environment. This article describes the conceptual design, research framework, evaluation components, and analytic strategies that are guiding the evaluation of this demonstration research endeavor. The ASSIST evaluation is a unique analysis of the complex relationships between the social context, public health activity at the state level, tobacco use, and individual behavior. The measures of tobacco control activity developed for this evaluation may be useful in ongoing national cancer control surveillance efforts, and the lessons learned will enhance the development of tobacco control programs.

THE AMERICAN STOP SMOKING INTERVENTION STUDY

Conceptual Framework and Evaluation Design

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EVOLUTION OF PUBLIC HEALTH PROMOTION APPROACHES

Reducing tobacco use, especially cigarette smoking, is a public health priority because smoking is the largest preventable cause of death and disability

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in the United States (Burns, Garfinkel, and Samet 1997; Office on Smoking and Health 1982). Public health approaches aimed at reducing the disease burden associated with risk factors such as tobacco use have focused primarily, over the past 20 years, on changing the behaviors of individuals. Those approaches have used a variety of tactics and strategies, including clinical treatment, education, social marketing techniques, mass media campaigns, and coalitions of community organizations to promote smoking cessation, as well as weight loss, physical activity, and blood pressure control (Schwartz 1987; Farquhar et al. 1984; Blackburn et al. 1984; Greenwald and Sondik 1986). Although these earlier endeavors recognized the importance of working with the community to change attitudes and environmental factors, their primary objective was to encourage behavioral change, primarily through the application of individually focused activities (such as smoking cessation) (Bracht 1990; National Cancer Institute 1991). For example, in the late 1980s and early 1990s, the Community Intervention Trial for Smoking Cessation (COMMIT) mobilized community organizations to reduce tobacco use by changing attitudes and behaviors regarding cigarette smoking and by increasing the demand for smoking-cessation services (Lando et al. 1995; Pomrehn et al. 1990-91). Measures of COMMIT's effectiveness included changes in cigarette consumption, smoking prevalence, and smoking cessation (individual-level outcomes) (National Cancer Institute 1995; COMMIT Research Group 1991, 1995a, 1995b).

A major shift in focus occurred in 1991: The American Stop Smoking Intervention Study (ASSIST) was initiated to prevent and reduce tobacco use primarily through the application of policy-based approaches to alter the social-political environment (macrolevel focus) (Shopland 1993; Manley, Lynn, et al. 1998). Measures of program effectiveness include individual-level outcomes (e.g., reductions in cigarette consumption and smoking prevalence) but also macrolevel changes (e.g., enactment of policies and legislation, increase in the coverage of tobacco-related issues in the media). This article describes the conceptual design and research framework that is guiding the ASSIST evaluation, the evaluation components, and the analytic strategies that address the challenges presented by such a large, complex demonstration project.

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ASSIST PROGRAM OVERVIEW

ASSIST is the largest, most comprehensive tobacco control project ever undertaken by the U.S. government. In October 1991, 17 state health departments were awarded contracts by the National Cancer Institute (NCI) to develop and implement the ASSIST project, with the overall goal to demonstrate that the application of statewide tobacco prevention and control programs and policies would reduce cigarette consumption and smoking prevalence. NCI formed a partnership with the American Cancer Society to accomplish this goal. The American Cancer Society provided additional resources to the project in the form of staff and volunteer resources and in-kind contributions (COMMIT 1995b; Manley, Lynn, et al. 1998).

ASSIST was designed to effect change in a diverse population: The ASSIST states have a combined population of 91 million people, more than a third of the population of the United States. The ASSIST population includes more than 10 million African Americans and 7 million people of Hispanic or other racial or ethnic minority groups (Manley, Lynn, et al. 1998).

ASSIST's statewide tobacco control plan is delivered by a network of state and local coalitions. The ASSIST coalitions were charged with developing and implementing interventions through four major channels: worksites, schools, health care settings, and community groups (COMMIT 1995b; Manley, Lynn, et al. 1998). The principal focus of the interventions is to alter the environmental and social influences affecting the population's use of tobacco. Interventions include (a) developing media advocacy skills to increase protobacco control media coverage; (b) strengthening support for local and state clean indoor air laws, reducing the easy access that youths have to tobacco products, limiting tobacco advertising and promotion, especially the targeting of children, women, and minorities, and increasing tobacco taxes; and (c) increasing the demand for smoking cessation services.

ASSIST EVALUATION MODEL

CONCEPTUAL DESIGN

ASSIST represents an ecological systems model, sometimes referred to as "the new public health," an approach that focuses on changing the social, cultural, economic, and physical environmental factors that influence health

behaviors (McKinlay 1993; Sallis and Owen 1997). An ecological systems model is dynamic and synergistic and is a means of explaining complex, nonlinear processes (Wallach and Dorfman 1996; Thompson et al. 1991). Because ecological or environmental change (macrolevel change) occurs incrementally and at a modest pace, multiple outcome points (initial, intermediate, and final) are needed for tracking the continuum of change as it occurs over the course of the project (Von Bertalanffy 1968; Green and McAlister 1984; Diez-Roux 1998; McKinlay 1996). For example, it might be expected that reductions in smoking prevalence would lag behind modifications in policy and social norms and behind reductions in cigarette consumption, but that over time, an effect on prevalence should be measurable (Pierce et al. 1994; Manley, Pierce, et al. 1998). Therefore, initial signs of change, such as in the strength of policy at the state level, could serve as an early indicator of the effect of the intervention. These societal-level markers have been labeled "upstream outcome measures" (McKinlay 1996).

TOBACCO CONTROL RESEARCH FRAMEWORK

Key Constructs

To put the evaluation in perspective, a research framework (see Figure 1) has been developed to explain the sequential process of change resulting from statewide tobacco control efforts. The framework consists of key constructs (i.e., groupings of related variables used to index or measure a moderately abstract concept) that may impede or promote progress toward the final outcomes of reducing cigarette consumption and smoking prevalence. Table 1 delineates these key constructs and the variables that will be used to measure them.

The first construct is resources committed to tobacco control efforts. The resource construct will include variables to assess states' budgetary expenditures for tobacco control. The next construct is the capacity to implement tobacco control activities. This construct includes variables assessing the number of state personnel, state-level agencies, and local coalitions committed to tobacco control. This capacity construct will measure the extent to which specific structures and linkages have developed among key state agencies and between state agencies and local coalitions or advocacy groups. Several studies have demonstrated that these linkages can be measured with quantitative indicators (Van de Ven and Ferry 1980; Himmerlman, Luxenberg, and Schmitz 1995). The next construct is antitobacco efforts and will

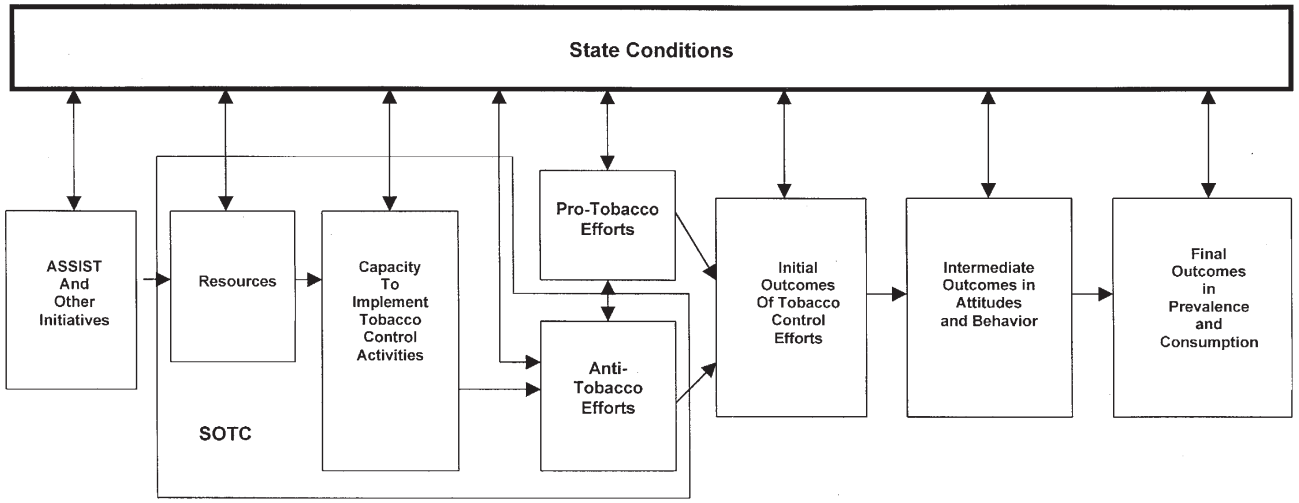

Figure 1: Tobacco Control Research Framework
NOTE: ASSIST = American Stop Smoking Intervention Study; SOTC = Strength of Tobacco Control.

TABLE 1: Key Elements and Outcome Measures of the Tobacco Control Research Framework

	Variables
Key Constructs	
Resources[a]	Dollars expended for tobacco control Source of funds for tobacco control
Capacity to implement tobacco control activities[a]	Number of state-level tobacco control personnel Capability of state organization to provide surveillance, training, and technical assistance Number of state organizations involved in tobacco control Frequency and type of contact between organizations Linkages between state and local tobacco control
Antitobacco efforts[a]	Quality of state tobacco control plan Comprehensiveness of state tobacco control plan Type of tobacco control strategies Comprehensiveness of state tobacco control effort
Protobacco efforts	Advertising dollars Legislative activities Other activities
State conditions	Age, education, population size, poverty status, race/ethnicity, gender, urban/rural Economic value of tobacco from agricultural, manufacturing, and processing (percentage of gross state product)
Outcome measures	
Initial outcomes	Rating of local and state tobacco control policies Percentage of workers covered by clean indoor air policies and workplace smoking bans Media advocacy score Cigarette price/tax
Intermediate outcomes	Behavior change Attitudes
Final outcomes	Prevalence Consumption

a. Summarized to form Strength of Tobacco Control (SOTC).

include whether a state has a comprehensive tobacco control plan and the extent to which its focus has included policy change and media advocacy activities.

In the research framework, these three constructs (resources, capacity, and antitobacco efforts) will be summarized to form an overall exposure measure of tobacco control efforts at the state level: strength of tobacco control (SOTC). Instead of measuring the individual effects of all the different tobacco control programs, this exposure measure will summarize this complex construct and the multiple facets and components of tobacco control efforts. SOTC will serve as an indirect measure for the program effects of ASSIST.

An important construct often ignored in evaluations of tobacco control impact is protobacco efforts that influence state efforts. The issue of tobacco industry activities, including their expenditures, is at the center of the national debate in Congress over the future of the tobacco industry. Protobacco efforts must be seen as a strong countervailing force that impedes achievement of tobacco control intervention objectives. One possible variable that might serve as a proxy measure of this construct is the amount of advertising and marketing expenditures in each state. In addition, the number of tobacco lobbyists and the presence of preemptive state tobacco control legislation or smokers' rights legislation are other possible sources of information (Samuels and Glantz 1991; Aguinaga et al. 1995; Goldstein and Bearman 1996). We will be able to quantify only a small fraction of these activities; however, this will be the first time that this important construct will be quantified in an assessment of statewide tobacco control outcomes. Finally, the research framework also includes state conditions as a construct comprising the important demographic and economic conditions in the state that contribute to the outcomes. For example, the impact of the tobacco industry on state economies will be measured by assessing the multiple sectors of the state economy that benefit from tobacco growing, manufacturing, and other activities.

Outcome Measures

Tobacco control efforts produce many types of change (see Table 1). Initial outcomes will be measured at both the individual level (micro) and the state level (macro). For example, a workplace tobacco policy, a primary intervention objective, is an initial outcome. Workplace tobacco policies can be self-imposed by employers and measured by individuals responding to a survey, or they can be mandated by state or local legislation and measured by a rating of the state or local legislation. In addition, a measure of media advocacy will be developed. Intermediate outcomes include changes in smoking behavior (quit attempts), changes in attitudes, and changes in the percentage

of the population reporting smoking bans in their homes. Final outcomes include changes in consumption levels and prevalence rates as well as in initiation rates and quit ratios. Smoking initiation rates among youth during the late 1980s and 1990s will be created retrospectively from cross-sectional survey data, the Tobacco Use Supplements to the Current Population Survey (CPS) (Centers for Disease Control and Prevention 1995).

The analyses of multiple outcomes (e.g., tobacco consumption, quit ratios, initiation rates, delay in age of initiation, changes in workplace policies, and media exposure at their different levels: initial, intermediate, final), in addition to smoking prevalence outcomes, are critical to understanding the relationships and timing of the various components of the tobacco control framework. From the California experience, it is apparent that changes in tobacco consumption can be seen sooner than changes in prevalence (Pierce et al. 1994). Changes in prevalence as a consequence of an intervention result from a complex mixture of changes in quitting, initiation, delays in the age of initiation, and the ability to affect these in the entire population examined. Tobacco consumption may also change as a consequence of several factors, such as the number of people beginning to smoke, the number of people quitting completely, and the number of smokers cutting down the number of cigarettes smoked; however, tobacco consumption is a more sensitive measure of tobacco control than smoking prevalence because it is a continuous measure that is measured frequently over time, resulting in many more measurements with a better basis for estimating trends in a time-trend analysis (Wun and Kessler 1995).

RESEARCH QUESTIONS

The ASSIST evaluation is guided by a series of research questions (see Table 2). The first question is whether the 17 ASSIST states will achieve lower tobacco consumption rates and lower smoking prevalence than all other states (Kessler et al. 1996). However, the evaluation design goes beyond this direct comparison of ASSIST states with all the other states. The evaluation will determine the relationship between exposure to tobacco control efforts (i.e., as measured by SOTC) or initial outcomes and levels of tobacco consumption and prevalence across all 50 states and the District of Columbia. In other words, did states with higher SOTC scores or a higher initial outcome score have lower tobacco usage? We will also identify the practices and approaches that were most likely associated with successful implementation of state-level tobacco control programs.

TABLE 2: American Stop Smoking Intervention Study (ASSIST) Research Questions

Primary evaluation questions
What is the effect of ASSIST on cigarette consumption and smoking prevalence rates (final outcomes)?
What is the relationship between ASSIST and SOTC (resources, capacity, and antitobacco efforts)?
What is the relationship between SOTC and cigarette consumption and smoking prevalence rates?
What is ASSIST's effect on initial outcomes (work site smoking bans, legislative scores, media advocacy scores, cigarette price)?
How are the initial outcomes related to the final outcomes?
What is the relationship between SOTC and the initial outcomes?
Did ASSIST modify the effects of the initial outcomes and/or SOTC's effects on the final outcomes?
Selected secondary evaluation questions
Which key variables of SOTC are associated with final outcomes?
Which key variables of the initial outcomes are associated with the final outcomes?
What is the relationship between protobacco influences and state conditions, and how are they associated with SOTC, initial outcomes, and final outcomes?

NOTE: SOTC = Strength of Tobacco Control.

PRIMARY DATA SOURCES

Tobacco Use Supplement to the CPS

The Tobacco Use Supplement to the CPS is the principal source for measuring intermediate outcomes, some final outcomes (prevalence, initiation rates, and quit ratios), and for assessing workplace tobacco policy, an initial outcome. The CPS is a household, interviewer-administered survey (25% personal interview, 75% telephone interview) of the civilian noninstitutionalized population. It has been conducted monthly since 1950 by the U.S. Bureau of the Census to provide estimates of employment, unemployment, and other characteristics of the general labor force, the population as a whole, and various subgroups of the population (Hansen 1985). All initial household contacts are in person. It was chosen for ASSIST because it is the only ongoing survey funded by the federal government that (a) provides a sample size sufficiently large from each state to detect the relatively small differences in changes in smoking behaviors and prevalence between ASSIST and non-ASSIST states and (b) uses a consistent methodology for collecting its data across all the states and the District of Columbia (Kessler et al. 1996; Hansen 1985; Shopland et al. 1996).

A special Tobacco Use Supplement to the CPS, sponsored by the NCI, was developed in 1990 for the ASSIST project; it includes questions about workplace policies, norms, attitudes toward tobacco use, physician and dentist advice on smoking cessation, and individual patterns of smoking and use of smokeless tobacco. The supplement consists of 40 self-report items that are asked of all persons residing in sampled households. NCI contracted with the Bureau of the Census to conduct the Tobacco Use Supplement to the CPS over 3 time periods during the course of ASSIST (baseline: 1992-1993; interim: 1995-1996; final: 1998-1999). Approximately 80% of the interviews were completed by self-respondents. The remaining 20% of interviews were obtained by proxy, for only those questions limited to tobacco prevalence. Approximately 295,000 individuals, 15 years of age and older, responded to the baseline survey and about 250,000 to the interim survey. The overall response rate for the interim supplement was 86% (that is, 86% of eligible individuals—those 15 years or older in households interviewed for the CPS—responded to the supplement). (The nonresponse rate to the basic CPS for that time period was 6.5%.)

Tobacco Consumption

Additional data sources for tracking changes in tobacco use (final outcomes) are tobacco sales tax data compiled monthly by The Tobacco Institute (The Tobacco Institute 1993). The ASSIST evaluation will include analyses of tobacco consumption in addition to analyses of smoking prevalence because it is likely to be a more sensitive measure of intervention effects than prevalence measures and may identify the effects of tobacco control efforts at an earlier stage in the process of change.

Policy Database

The State Cancer Legislative Database (SCLD), developed and maintained since 1989 by NCI, is the primary data source for measuring changes in state tobacco control policies (National Cancer Institute, State Cancer Legislative Database n.d.). The SCLD includes information about all enacted state legislation related to cancer control, including tobacco control. Information about each law, including an abstract describing the provisions of each law, is maintained in a single computerized record. Information on pending legislation is also collected. The ASSIST legislative analysis will include a content analysis of each piece of legislation tracked, using rating scales to quantify key aspects of the legislation, such as its breadth,

restrictiveness, and enforcement provisions; actual enforcement will not be tracked (Alciati et al. 1998).

Media Database

A major effort of ASSIST is media advocacy to increase news coverage of activities and actions to promote tobacco control. All articles appearing in daily newspapers in all 50 states plus the District of Columbia concerning tobacco-related issues are clipped by a national service. The database currently has 83,000 tobacco-related articles. The ASSIST Coordinating Center reviews the articles for relevance and sorts them according to policy content (clean indoor air, restriction of access to minors, economic incentives, advertisement and promotion of tobacco, or other), frame of the story (protobacco control, antitobacco control, or neutral), type of coverage (news story, cartoon, letter to editor, editorial), prominence (whether they appear on the front page of the newspaper), and origin of story (local or national). These data will provide a base for unbiased, nonintrusive comparisons of ASSIST and non-ASSIST sites on their exposure to tobacco-related articles as well as for state-specific analyses. Analyses of these data will provide information about the quantity and types of media coverage, which can then be related to initial and intermediate outcomes.

EVALUATION CHALLENGES AND SOLUTIONS

ASSIST was designed as a demonstration and implementation research project (NCI–Cancer Control Phase V) (Greenwald, Cullen, and McKenna 1987). The evaluation design for this large, complex demonstration research project must address a number of analytical challenges, including possible site selection bias (nonrandomization of sites), diffusion of ASSIST activities to other states, the active introduction of ASSIST-like intervention in non-ASSIST states by other national tobacco control programs, and the influence of independent factors and competing influences on smoking and tobacco control policies.

Site Selection Bias

States were awarded ASSIST contracts based on competitive proposals and their characteristics rather than any random assignment (Hall et al. 1992; Stotts et al. 1994). At baseline, the ASSIST states had less than a 1 percentage point higher average prevalence of smoking (for ages 18 and older) than the

TABLE 3: Comparison of ASSIST to non-ASSIST States at Baseline for Population 18 Years of Age and Older

Variable	*ASSIST*	*95% CI (±)*	*Non-ASSIST*	*95% CI (±)*	*Non-ASSIST Without CA*	*95% CI (±)*	p *values*[a]
Prevalence	25.2	1.3	24.4	0.94	24.6	0.91	0.35
Per capita tobacco consumption	10.6	0.94	10.5	0.80	10.6	0.80	0.89
Percentage workplace ban	45.6	4.3	46.8	2.9	46.5	2.9	0.63
Percentage female	52.4	0.43	52.0	0.40	52.1	0.40	0.22
Percentage below poverty	13.9	1.7	14.4	1.5	14.3	1.5	0.69
Percentage below ninth grade	7.7	1.2	7.7	0.99	7.6	0.99	0.97
Percentage Black, Non-Hispanic	8.8	3.7	10.6	4.4	10.7	4.5	0.56
Percentage Hispanic	5.1	3.8	4.7	2.2	4.1	1.9	0.85
Percentage farm commodities (1993)	2.7	2.8	1.5	1.9	1.5	1.9	0.51
Price per pack of cigarettes ($)[b]	1.87	0.11	1.89	0.06	1.88	0.06	0.79
Mean age	44.1	0.38	43.9	0.43	44.0	0.44	0.52
Mean state population (million)	4.017	1.428	3.490	1.546	2.915	1.090	0.67

NOTE: ASSIST = American Stop Smoking Intervention Study.
a. *p* values correspond to ASSIST–non-ASSIST comparison.
b. Includes sales and excise taxes.

other states (25.2% and 24.4%, respectively; $p = .35$) and wide variations of state conditions, preintervention levels of tobacco control activities, and policies. Table 3 compares ASSIST states and non-ASSIST states on some of these key variables. The general effect of the ASSIST program will be summarized in a very parsimonious regression model that will include all 50 states and the District of Columbia. Covariates will be used to control for the nonrandomization and the baseline differences of the states as well as to reduce the variability of estimates.

Diffusion, Contamination, and Secular Trends

A large amount of natural contamination from parallel antitobacco activities was expected to occur throughout the ASSIST project. A long-term increase in tobacco control activities has occurred during the 34 years since the 1964 Surgeon General's report on tobacco. In fact, national dissemination of tobacco control strategies has been encouraged by NCI as a means of achieving the Healthy People 2000 goals. Accompanying these activities was a steady, gradual decline in smoking prevalence until about 1990, when the rate leveled.

ASSIST was designed as a catalyst for tobacco control efforts. After ASSIST, initiatives such as the Centers for Disease Control and Prevention's IMPACT States (1993) and the Robert Wood Johnson Foundation's SmokeLess States (1994) were funded to implement tobacco control efforts programs in all 50 states. Although these programs may have been influenced by ASSIST, they occurred independently and concurrently. The analytical approach to address these challenges will be described in the following section.

ANALYTICAL APPROACH

UNIT OF ANALYSIS

Because the state is the level at which the ASSIST assignments were made, the unit of analysis will be the state. Many constructs in the tobacco control evaluation framework are measured only on the state level. However, tobacco control research on the state level will provide a maximum of only 50 units (51 units including the District of Columbia). In this case, quantitative analysis, such as regression, will be limited to relatively few variables in any

modeling of each outcome analyzed. With a maximum of only 51 observations, even a modest degree of random variation can severely limit the power of the analysis to detect an effect, especially for outcomes such as smoking prevalence, initiation, quit ratios, and workplace smoking bans, which are measured infrequently over time from the Tobacco Use Supplement to the CPS. Outcomes such as media exposure, state legislative policies, and tobacco consumption may have more power to detect an effect because of the time-series nature of the data. Thus, some small but important differences in the context of tobacco control may not be statistically significant.

Using the estimates from the CPS of the standard deviation of the change in state-level smoking prevalence over the periods 1989 to 1992-1993 and 1985 to 1992-1993 (2.11% and 2.51%, respectively), we computed the power for differences in state-level changes in smoking prevalences of 1.5% to 2.5% between the 17 ASSIST and the 34 non-ASSIST states. The power was .76 and .63 for a difference of 1.5%, and .99 and .95 for a difference of 2.5% between ASSIST site changes and non-ASSIST site changes, corresponding to the two estimates of standard deviations for the two time periods. All of these calculations are for a one-tailed test, with an alpha = 0.05.

DIFFERENT ANALYTICAL APPROACHES

In addition to changes in smoking prevalence and tobacco consumption, a number of other important final, intermediate, and initial outcomes will be evaluated, as presented in Table 1 and mentioned above. Because the various outcomes are measured from different sources, take different forms, and are captured with different frequencies over the course of the ASSIST project, they require different methods of analysis. Here, we briefly describe the two major categories with some illustrations of outcome variables that fall under each category of analytic approach.

First, outcomes that are cross-sectionally measured infrequently on individuals in the Tobacco Use Supplement to the CPS (1992-1993, 1995-1996, 1998-1999) will be analyzed with mixed-effects models, with adjustments for person-level and state-level covariates. Analysis will be conducted with the 1995-1996 data as the endpoint for the interim analysis or with the 1998-99 data as the endpoint for the final analysis. Thus, each analysis will examine only one point in time, adjusted for 1992-1993 baseline data. Examples of these outcomes are smoking prevalence, quit ratios, initiation rates, percentage of people at work sites with a total smoking ban, and percentage of people supporting a total smoking ban in their homes and in various public places. A two-stage method will be used to estimate the parameters in the

Question 1: What is the effect of ASSIST on smoking prevalence rates?

$P_e = \beta_0 + \beta_1 P_b + \beta_2 T + \beta_3 A + \gamma X + error$

where

- P_b = state-level smoking prevalence at baseline, 1992-93 (after adjustment for individual level covariates)
- P_e = state-level smoking prevalence at end, 1998-99 (after adjustment for individual level covariates)
- T = index representing the impact of the tobacco industry
- A = binary indicator of state ASSIST status
- X = demographic and economic state conditions (statistically selected)

Question 2: What is the relationship between ASSIST and Strength of Tobacco Control (SOTC) efforts?

$S_l = \beta_0 + \beta_1 S_b + \beta_2 T + \beta_3 A + \gamma X + error$

where

- S_l = SOTC over the intervention period
- S_b = SOTC at baseline 1992-93.

Question 3: What is the relationship between SOTC and smoking prevalence?

$P_e = \beta_0 + \beta_1 P_b + \beta_2 T + \beta_3 S_l + \gamma X + error$

Question 7: Is the relationship between SOTC and smoking prevalence different for ASSIST states than for non-ASSIST states?

$P_e = \beta_0 + \beta_1 P_b + \beta_2 S_l + \beta_3 A + \beta_4 S_l \times A + \beta_4 T + \gamma X + error$

where

- $S_l \times A$ = the interaction between SOTC over the intervention period and ASSIST status.

Figure 2: Regression Models Used to Analyze Infrequently Measured Outcomes for Selected Questions for Illustration

NOTE: ASSIST = American Stop Smoking Intervention Study.

mixed-effects models (Gail et al. 1996). In the first stage, the outcome variable is regressed on sociodemographic variables (not including the exposure variable such as ASSIST status), using the observations on individuals from the combined baseline and endpoint surveys. For example, in the analysis of smoking prevalence, smoking status of individuals is regressed on their sociodemographic characteristics using logistic regression. In the second stage, residuals from the first stage regression are aggregated into state means, and these means are regressed using multiple linear regression on covariates for state conditions and on the exposure variable. State conditions can include the economic dependence on tobacco and demographic variables aggregated to the state level (see Tables 1 and 3 and Figure 2). Two-stage estimation is used instead of single-stage maximum likelihood estimation (MLE) because the sample weights from the CPS can be incorporated into

the regressions at each stage of estimation in the two-stage approach, whereas presently, it is not known how to correctly use the sample weights in MLE for mixed-effects models (Pfeffermann et al. 1998; Graubard and Korn 1996). In addition, the two-stage approach requires fewer distributional assumptions than the MLE approach.

Second, outcomes that are continuous and measured frequently at regular time intervals for each state will be analyzed using linear mixed-effects models with time-trend effects and adjustments made for state-level covariates. These outcomes include per capita tobacco consumption, media advocacy scores, and cost of cigarettes. For per capita tobacco consumption, the data will be first deseasonalized and then analyzed using the mixed-effects models. We plan to use MLE for these mixed-effects analyses, with random coefficients for the exposure and time-trend effects and possibly an autoregressive correlation of the error terms within state over time. If the time trend effects are not linear, then we will include quadratic time trend effects. For example, in an analysis of the effect of ASSIST on per capita tobacco consumption, the mixed-effects model will estimate differences between the time trends in tobacco consumption between the ASSIST and non-ASSIST states using interaction effects between time and ASSIST status. In addition to the analyses using MLE estimation, we will examine a two-stage estimation approach that is more robust to potential miss-specified distributional assumptions than MLE under linear time trend effects. In the first stage, a separate linear time trend in tobacco consumption is modeled for each state for two time periods (prebase line and intervention periods). The beta coefficients (slopes) for the intervention period from this first stage analysis is used as the dependent variable in a second-stage model with relevant covariates and the prebase line slopes. This second-stage model also includes the variable of interest, for example, ASSIST and non-ASSIST, SOTC, or index of Initial Outcomes as appropriate. The regression coefficient of the variable of interest represents the effect of that variable, for example, ASSIST, on tobacco consumption trends after adjusting for prebaseline trends in consumption and other covariates.

EXPRESSION OF OUTCOMES

Figure 2 illustrates regression models formulated to answer some key representative questions from Table 2. In these models, the differences in the levels of baseline smoking prevalence or baseline SOTC among the states are adjusted in the analysis by including the baseline variable as an independent variable in the regression model (a regression adjustment for baseline). This

approach for adjusting for baseline is more flexible and potentially more powerful than analyzing the simple difference (between the smoking prevalence or SOTC value at the end of the ASSIST intervention period from the value at the baseline time) as the dependent variable (Cohen and Cohen 1991; Samuels 1986). Empirical exploration using earlier Tobacco Use Supplements to the CPS (1985, 1992-1993) compared the power of these two approaches along with a relative change approach analyzed as the dependent variable in the regression model without including baseline prevalence as an independent variable. This relative change is a ratio of the change in the point smoking prevalence over the course of the study to the point smoking prevalence at baseline. Results from this exploration suggested that the power of the relative change was about the same as that of a simple change, both lower than the power obtained using the regression adjustment approach.

ADJUSTING FOR FACTORS SUCH AS STATE CONDITIONS (E.G., DEMOGRAPHICS)

State conditions such as demographics (e.g., sex, age, race/ethnicity, poverty status, education, urban/rural, population size) and economic dependence on tobacco (agricultural, manufacturing, and processing cash receipts as a percentage of the gross state product) may be confounders in these analyses because they can influence the success of tobacco control and could differ between ASSIST and non-ASSIST states (although this was not evident from Table 3). Two common alternative methods for adjusting for such confounding variables have been considered: (a) using a direct adjustment method as is commonly used for adjusting age for cancer incidence, and (b) using a regression model by including the factors as independent variables in the model. We will use the second method because it offers more stable estimates when adjusting for variables such as race (some states may have small numbers of non-White racial groups).

Because the mixed-effects models use the state as the unit of analysis, we are limited in the number of state conditions that should be used as covariates for adjustment. Therefore, we explored alternative methods of adjusting for state conditions that would reduce the number of covariates in the models. We considered using a propensity score (the predicted probability of a state being selected as an ASSIST state as estimated from a logistic regression of state conditions) in place of the state conditions as independent variables (Drake 1993). Also, we considered an "all possible regressions" method using Mallows minimum Cp criteria to choose the most predictive set of state conditions (SAS Institute 1989). Using the data from earlier Tobacco Use

Supplements to the CPS, we also conducted an empirical investigation of these methods. The propensity score method was unable to find any combination of state condition variables that distinguished between ASSIST and non-ASSIST states and, as a result, was not useful in adjusting for these variables in the mixed-effects models. It was decided to use the "all possible regressions" method because the subset of state condition variables selected in this empirical investigation were more predictive of the smoking prevalence outcome than the propensity score. Unfortunately, software is not available for using the Mallow Cp criteria with MLE of the mixed-effects models. In these analyses, we will select the best subset of state condition variables by using the "forward stepwise regression approach" and a criterion for retaining only those adjusting independent variables that are statistically significant at the two-tailed 0.05 level.

SUMMARIZING COMPLEX CONSTRUCTS

The success of this evaluation depends heavily on finding parsimonious representation of complex constructs (such as SOTC) throughout the ASSIST research framework (COMMIT 1995a, 1995b). z-scores will be created for each continuous variable in a complex construct. A correlation matrix of z-scores for combinations of variables for any given construct—for example, the SOTC—will be examined to see whether any variables are redundant (looking for colinearity) and can be eliminated. Then, the z-scores will be summed to create an overall score for each construct of interest. Weighting of component variables in a construct will be used when appropriate and available from consensus or previous experience. For some more complex constructs, a principal components approach will be considered. Preliminary versions of some summary measures and parts of these scores based on earlier Tobacco Use Supplements to the CPS (1992-1993) data are under development.

CONCLUSION

In conclusion, the evaluation of ASSIST provides an opportunity to generate invaluable information about the delivery and impact of the largest federal tobacco control initiative. Through the development and testing of a research framework of tobacco control, based on an ecological systems model, the ASSIST evaluation will provide a unique research opportunity to investigate complex relationships between the social context, public health activity at the

state level, tobacco use, and individual behavior change. The new indices, databases, and analytical methods developed to address the challenges inherent in evaluating such a complex endeavor can be applied to future research and program initiatives. Thus, the lessons to be learned from this evaluation have the potential to enhance tobacco control program development in the future as well as other kinds of initiatives that seek to change health behavior through a macrolevel, systemswide approach.

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